

PATENT  
Atty. Docket No. 0999.001  
USSN 08/349,489

Remarks

According to the Examiner, claims 1-3, 6-8, and 15 are currently pending in the instant application. However, Applicant believes that claims 1-3, 5-9 and 15 should be pending based on the Restriction Requirement in Paper No. 4, mailed March 29, 1996, and on Applicant's election in Paper No. 5. In each of those papers, claims 1-3, 5-9 and 15 are referenced. Indeed, claim 6 depends from claim 5, which in turn depends from claim 1. Therefore, Applicant will proceed to discuss all of the claims as though claims 1-3, 5-9 and 15 are pending.

Claim 1 has been amended. The amendment to claim 1 finds support throughout the specification and, for example, in Example 2, beginning on page 24, line 26 of the specification. Entry of the amendment is respectfully requested. Applicant will now address the rejections of the claims.

35 USC §112, First Paragraph Rejection:

Claims 1-3, 5-9, and 15 stand rejected under 35 USC §112, first paragraph. The Examiner alleges that the specification "does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims". Applicant respectfully traverses this rejection. Applicant requests that the §112, first paragraph rejection be withdrawn.

Claim 1, upon which the rest of the pending claims depend, has been amended to recite that the bispecific antibody is administered to the patient "in an amount sufficient to induce production of antibodies to said second antigen in said patient". One feature of Applicant's discovery is that the immune response induced by administration of the bispecific antibodies set forth in the claims induces production of antibodies to the second antigen. Such an immune response was not expected.

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However, it is clear from the specification that Applicant has enabled a person skilled in the art to administer bispecific antibodies, falling within the limitations of the claims, in order to induce the desired antibody response. Example 1 sets forth treatment regimens. The Examiner has pointed to no deficiency in the treatment regimen. Therefore, since the specification must be presumed by the Patent Office to be enabling the rejection of the claims as amended may be withdrawn.

The Examiner also states that the specification fails to enable one of skill in the art how to induce all of the different forms of immune responses. Applicant respectfully traverses this rejection. Claim 1, as amended, clearly points out the features of Applicant's invention. That is, the antibody is to be administered in an amount sufficient to induce production of antibodies to said second antigen in the patient receiving the bispecific antibody. Thus, the amendment to claim 1 effectively moots the rejection and the rejection may be withdrawn.

Before leaving this rejection, Applicant wishes to comment on the Examiner's position that the specification does not teach that bispecific antibodies would be useful as vaccines. Applicant wishes to express disagreement with the Examiner's assertion, even though the point may be moot in light of the amendments to claim 1. Finally, Applicant notes that to the extent that the claims have been narrowed by the amendment to claim 1, Applicant reserves the right to pursue such claim scope as was present in the originally filed claims in future continuing and divisional applications.

35 USC §103 Rejection:

Claims 1-3, 5-9 and 15 stand rejected under 35 USC §103 as being unpatentable over Hsieh-Ma et al., or Weiner et al., or Ring et al., in view of Fanger et al. Applicant respectfully traverses this rejection. Claim 1 has been amended as discussed above to point out that one of the characteristics of the immune response is that antibodies to the second antigen

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are generated by the patient. In the discussion of each of Hsieh-Ma et al., Weiner et al., and Ring et al., the Examiner concedes that the references do not disclose induction of immune responses. Applicant agrees with the Examiner that none of these three references discloses the induction of an antibody response. Applicant also believes that Fanger is similarly deficient. Thus, none of the references cited by the Examiner alone or in combination contain all of the elements of the invention as currently claimed by Applicant.

Conclusion

Applicant believes that all of the Examiner's concerns raised in the Office Action have been addressed. An early allowance of the claims is therefore earnestly solicited. If further issues remain, Applicant's representative, Paul B. Savereide, may be reached at the telephone number listed hereinbelow.

Respectfully submitted,

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